JUN 1 5 2001

510(k) Summary
Marconi "MX 8000 v5.0"

K010817

(As required by 807.92)

Submitter:	Marconi Medical Systems, Inc. 595 Miner Road Highland Heights, Ohio 44143
Contact	Robert L. Turocy Telephone: 440 483 3528 FAX: 440 483 1116
Date of Summary:	May 25, 2001
Device Name (Proprietary Name):	MX8000 v5.0
Common Name:	Computed Tomography X-Ray System
Classification Name:	Computed Tomography X-Ray System
Classification	Class II in 21 CFR 892.1750 Computed tomography x-ray system Product Code 90 JAK
Performance Standards	21 CFR 1020.30 – 1020.33 as applicable.

Substantial Equivalence to legally marketed device:
The MX8000 v5.0 is of comparable type and substantially equivalent to the legally marketed device currently in commercial distribution, namely the MX8000 (initially identified as Volumax), in CDRH Document Control No K982060. This opinion is based on the fact that comparing the MX8000 with the MX8000 v5.0 reveals that both devices comply with the same or equivalent standards and have the same or equivalent intended uses.

Device Function:
The MX80005 v5.0 is manufactured in accordance with the FDA GMPs and the Performance Standards in 21 CFR 1020. 30 – 33, and voluntary standards for safety and effectiveness (UL2601) which mandate that the MX8000 v5.0 is tested to demonstrate that hazards, i.e., electrical, mechanical, and radiation have been minimized. The MX 8000 v5.0 is a high-power, ultra resolution; multislice computed tomography system capable of up to four slices per second acquisition rate using dual detector technology. The MX 8000 v5.0 delivers scanning features to perform cardiac CT imaging, functional CT, low-dose screening, CT Angiography (CTA), isotropic detail, and visualization of hollow organs of the body.

Intended Use:
The MX8000 v5.0 is a Computed Tomography X-Ray System intended use is to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories. The MX8000 v5.0 is under the control of health care professionals who are trained and responsible for computed tomography examinations.

Technological Characteristics:
The MX 8000 v5.0 has the same technological characteristics as the MX 8000. In addition, the MX 8000 v5.0 is similar in design, material, second-generation multi-slice CT system as the MX 8000. The MX 8000 v5.0 represents current state-of-the-art technology, therefore, equivalent to the legally marketed device, the MX8000 CT System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2001

Mr. Robert L. Turocy
Regulatory Affairs & Compliance Manager
Marconi Medical Systems, Inc.
595 Miner Road
HIGHLAND HEIGHTS OH 44143

Re: K010817
MX8000 v5.0 (CT Device)
Dated: March 16, 2001
Received: March 19, 2001
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Turocy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K 010817 Page 1 of 1

Device Name: MX8000 v5.0

Indications for Use: The MX8000 v5.0 is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This device may include signal analysis and display equipment, patient, and equipment supports, components and accessories.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010817

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)